

Docket No. 366325-120
US App. No. 09/340,338

IN THE CLAIMS

1-41. (Previously Canceled)

42. (Currently Canceled)

43. (Currently Amended) The delivery device of claim [42] 49, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

44. (Currently Amended) [The delivery device of claim 43,] A delivery device for treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the device does not comprise a backing layer, wherein the device does not comprise a release liner, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer, and wherein the disk comprises 70 to 95 wt% filmogenic polymer.

45. (Previously Added) The delivery device of claim 44, wherein the filmogenic polymer is polyvinyl pyrrolidone.

46. (Previously Added) The delivery device of claim 44, wherein the filmogenic polymer is gliadin.

47. (Currently Amended) The delivery device of claim [42] 44, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

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48. (Currently Amended) The delivery device of claim [42] 44, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

49. (Currently Amended) [The delivery device of claim 42,] A delivery device for treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the device does not comprise a backing layer, wherein the device does not comprise a release liner, and wherein the therapeutic agent is misoprostol.

50. (Currently Amended) The delivery device of claim [42] 44, wherein the therapeutic agent is a prostaglandin.

51. (Previously added) The delivery device of claim 50, wherein the therapeutic agent is prostaglandin E1.

52. (Currently Amended) The delivery device of claim [42] 49, wherein the disk further comprises a plasticizer in an amount of less than 30 wt%.

53. (Previously Added) The delivery device of claim 52, wherein the plasticizer is a polyethylene glycol (PEG).

54. (Previously Added) The delivery device of claim 53, wherein the polyethylene glycol is PEG 400.

55. (Currently Amended) The delivery device of claim [42] 49, wherein the delivery device is a transdermal device.

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56. (Currently Amended) The delivery device of claim [42] 49, wherein the delivery device is a transmucosal device.

57. (Previously Added) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the disk comprises 70 to 95 wt% filmogenic polymer.

58. (Previously Added) The delivery device of claim 57, wherein the filmogenic polymer is polyvinyl pyrrolidone.

59. (Previously Added) The delivery device of claim 57, wherein the therapeutic agent is misoprostol.

60. (Previously Added) The delivery device of claim 57, wherein the therapeutic agent is a prostaglandin.

61. (Previously Added) The delivery device of claim 60, wherein the prostaglandin is prostaglandin E1.

62. (Previously Added) The delivery device of claim 57, wherein the mixture of materials further comprises a plasticizer in an amount of less than 30 wt%.

63. (Previously Added) The delivery device of claim 62, wherein the plasticizer is a polyethylene glycol (PEG).

64. (Previously Added) The delivery device of claim 63, wherein the polyethylene glycol is PEG 400.

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65. (Previously Added) The delivery device of claim 57, wherein the delivery device is a transdermal device.

66. (Previously Added) The delivery device of claim 57, wherein the delivery device is a transmucosal device.

67. (Previously Added) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone and an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

68. (Previously Added) The delivery device of claim 67, wherein the therapeutic agent is misoprostol.

69. (Previously Added) The delivery device of claim 67, wherein the therapeutic agent is a prostaglandin.

70. (Previously Added) The delivery device of claim 69, wherein the prostaglandin is prostaglandin E1.

71. (Previously Added) The delivery device of claim 67, wherein the mixture of materials further comprises a plasticizer.

72. (Previously Added) The delivery device of claim 71, wherein the plasticizer is a polyethylene glycol (PEG).

73. (Previously Added) The delivery device of claim 72, wherein the polyethylene glycol is PEG 400.

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74. (Previously Added) The delivery device of claim 67, wherein the delivery device is a transdermal device.

75. (Previously Added) The delivery device of claim 67, wherein the delivery device is a transmucosal device.

76. (Previously Added) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone, an effective dose of a therapeutic agent suitable for treating erectile dysfunction and a plasticizer, wherein the device does not comprise a backing layer and wherein the device does not comprise a release liner.

77. (Previously Added) The delivery device of claim 76, wherein the therapeutic agent is misoprostol and the plasticizer is PEG 400.

78. (Previously Added) The delivery device of claim 76, wherein the therapeutic agent is a prostaglandin.

79. (Previously Added) The delivery device of claim 78, wherein the prostaglandin is prostaglandin E1.

80. (Previously Added) A delivery device for the treatment of erectile dysfunction in a patient, comprising a disk; wherein the disk is made of a mixture of materials comprising 70 to 95 wt% filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additive selected from the group consisting of a stabilizer, a solubilizer, and enhancer and a plasticizer.

81. (Previously Added) The delivery device of claim 80, wherein the at least one additive comprises an enhancer selected from the group consisting of a glycolipid, a

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non-esterified fatty acid, an aliphatic alcohol, a fatty acid ester of an aliphatic alcohol, a cyclohexanol, a fatty acid ester of glycerol, a glycol, an aliphatic alcohol ether of a glycol, and a surfactant.

82. (Previously Added) The delivery device of claim 80, wherein the therapeutic agent is a prostaglandin.

83. (Previously Added) The delivery device of claim 82, wherein the prostaglandin is prostaglandin E1.

84. (Previously Added) The delivery device of claim 82, wherein the at least one additive comprises a plasticizer.

85. (Previously Added) The delivery device of claim 84, wherein the plasticizer is a polyethylene glycol.

86. (Previously Added) A method of treating erectile dysfunction, comprising:

selecting a device comprising a disk, wherein the disk is made of a mixture of materials comprising a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction, wherein the disk comprises 70 to 95 wt% filmogenic polymer, wherein the device does not comprise a backing layer and wherein the device does not comprise a release liner;

wetting a penile surface; and

placing the device in contact with the wetted surface, thereby wetting the disk and delivering the at least one therapeutic agent to the penile surface in a time period that is desirable to obtain a positive response.

87. (Previously Added) The method according to claim 86, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle

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relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

88. (Previously Added) The method according to claim 86, wherein the therapeutic agent is selected from the group consisting of a prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

89. (Previously Added) The method according to claim 86, wherein the therapeutic agent is present in a range of 0.1-15 wt%.

90. (Previously Added) The method according to claim 88, wherein the therapeutic agent is misoprostol.

91. (Previously Added) The method according to claim 86, wherein the plasticizer is present in an amount that is less than 30 wt%.

92. (Previously Added) The method according to claim 91, wherein the plasticizer is a polyethylene glycol (PEG).

93. (Previously Added) The method according to claim 92, wherein the polyethylene glycol is PEG 400.

94. (Previously Added) The method according to claim 86, wherein the filmogenic polymer is a synthetic polymer.

95. (Previously Added) The method according to claim 94, wherein the synthetic polymer is polyvinyl pyrrolidone.

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96. (Currently Amended) The method according to claim [86] 112, wherein the filmogenic polymer is a plant protein.

97. (Previously Added) The method according to claim 96, wherein the plant protein is a prolamine.

98. (Previously Added) The method according to claim 97, wherein the prolamine is a gliadin.

99. (Previously Added) The method according to claim 86, wherein the time period is 5-100 minutes.

100. (Previously Added) The method according to claim 99, wherein the time period is 30-60 minutes.

101. (Previously Added) The method according to claim 86, wherein the penile surface is selected from the group consisting of (a) the shaft, (b) the glans and (c) both the shaft and the glans.

102. (Previously Added) A method of treating erectile dysfunction, comprising:

selecting a device comprising a disk, wherein the disk is made of a mixture of materials, wherein the disk is made of a mixture of materials comprising 90 to 95 wt% polyvinyl pyrrolidone, polyethylene glycol and an effective dose of misoprostol suitable for treating erectile dysfunction;

wetting a penile surface; and

placing the device in contact with the wetted surface, thereby wetting the disk and delivering the at least one therapeutic agent to the penile surface in a time period that is desirable to obtain a positive response.

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103. (Previously Added) The method according to claim 102, wherein the penile surface is selected from the group consisting of (a) the shaft, (b) the glans and (c) both the shaft and the glans.

104. (New) The delivery device of claim 57, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

105. (New) The delivery device of claim 57, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

106. (New) The delivery device of claim 67, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

107. (New) The delivery device of claim 67, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

108. (New) The delivery device of claim 76, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

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109. (New) The delivery device of claim 76, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

110. (New) The delivery device of claim 80, wherein the therapeutic agent is selected from the group consisting of a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

111. (New) The delivery device of claim 80, wherein the therapeutic agent is selected from the group consisting of prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

112. (New) The delivery device of claim 86, wherein the filmogenic polymer is a naturally occurring polymer.

113. (New) The delivery device of claim 57, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

114. (New) The delivery device of claim 80, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.